

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESAL PRICE LITIGATION

) **MDL No. 1456**
) **Master File No. 01-12257-PBS**
)
) **Judge Patti B. Saris**

THIS DOCUMENT RELATES TO:
State of California, *ex rel.* Ven-A-Care v.
Abbott Laboratories, *et al.*
03-cv-11226-PBS

) **LEAVE TO FILE GRANTED**
) **ON SEPTEMBER 11, 2006**
) **VIA ELECTRONIC ORDER**

**PLAINTIFFS' SUPPLEMENTAL SUBMISSION IN RESPONSE TO THE
COURT'S REQUEST FOR CLAIMS EXAMPLES**

During the May 22, 2006 hearing on Defendants’ Motion to Dismiss California’s First Amended Complaint in Intervention (FAC, filed August 25, 2005), the Court asked counsel for Plaintiffs if examples of claims for each drug at issue in the FAC could be provided. Counsel responded affirmatively. Specifically, the following colloquy occurred toward the end of the hearing:

THE COURT: Well, I think what [Defendants are] saying is that you should give me at least one claim. So you're the state. Give me one false claim for each category. Is that what you're saying?

MR. BREEN: Your Honor, if we were to attach -- I understand what they're saying.

THE COURT: I haven't actually gone that route but --

MR. BREEN: But if we're going to do that, I mean, if one claim or all the claims, all the claims we tried to figure it out, it would be five stories high at a minimum.

THE COURT: That's right, so I'm not going to require it. But let me just ask you this: Would you have an example of at least one for each kind of pricing fraud?

MR. PAUL: Your Honor, we can certainly provide that if the Court determines that that would help the system.

THE COURT: I wouldn't want them all, and I wouldn't demand them all. The question is, I will ask them that question, so -- because unlike some of the other cases I have where they're the consumer class actions and they're the sick old people, you're actually the state of California, so *I'm assuming you can come up with one example of each drug that was allegedly fraudulently billed. Is that*

right?

MR. PAUL: I appreciate your confidence, your Honor. We can.

THE COURT: Okay, is there anything else? We can do quick rebuttals, and then we can move on.

Transcript of May 22, 2006 Motion Hearing in Case No. 01cv12257-PBS, at 49:11-50:12

(Ex. A, emphasis added.)

Pursuant to the above quoted exchange, attached as Exhibit B are data lines documenting one electronically-submitted and processed claim for each drug that was fraudulently priced.¹ These claims are representative samples, one per drug, of the millions of Medi-Cal claim submissions which have been infected by the fraudulent pricing scheme alleged in California's FAC and portrayed in the unredacted pricing exhibits filed under seal. Exhibit C is a glossary explaining the titles for each column depicted in Exhibit B.

As set forth in detail within the FAC, this case is focused on the fraudulent prices reported by Defendants to California in drug pricing compendia, regarding drugs manufactured and sold by Defendants to providers who dispense those same drugs to millions of California Medicaid beneficiaries under the Medi-Cal program. FAC ¶¶ 27-42. Medi-Cal is administered by the California Department of Health Services (CDHS), and CDHS relies upon the prices reported by the Defendants to process the hundreds of millions of claims submitted by providers every year through its fiscal intermediary, Electronic Data Systems (EDS). *Id.* ¶¶ 32, 33, 35, 39. Claims are reimbursed based on the prices reported by the Defendants to California through First Data Bank (FDB) or other price reporting services, *id.* ¶¶ 32-35, with FULs being set by the

1. The information in Exhibit B represents a legible conversion of the flat file data that constitutes an actual claim. The flat file data does not contain field headings, which were provided here for purposes of clarity, as explained in Exhibit C. Plaintiffs also note that a complete claim record contains protected personal health information for all beneficiaries, under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 45 C.F.R. § 164.502(a), which information is not relevant and not provided here.

Centers for Medicare and Medicaid Services (CMS, formerly the Health Care Financing Administration (HCFA)) for some generic drugs during some periods at issue in the FAC using prices published by the Defendants, *id.* ¶¶ 31, 41, 48. A claim cannot be reimbursed, for the drugs at issue in the FAC, without the Defendants’ reported prices entering into the reimbursement calculus conducted by CDHS’s electronic claims processing and reimbursement systems. *Id.* ¶¶ 32-35.

As stated in the FAC, “Medi-Cal reimburses providers for drugs from most manufacturers at what is called the Cost of the Drug Product (CDP), which is the lowest of the drug’s Estimated Acquisition Cost (EAC), Federal Allowable Cost (FAC) [i.e., the Federal Upper Limit (FUL)], or Maximum Allowable Ingredient Cost (MAIC) for the Standard Package size, or the amount billed by the provider. EAC for a drug product is the Direct Price (DP) or Average Wholesale Price (AWP) minus a determined percentage. (CAL.CODE REGS. tit. 22, § 51513 et seq.).” FAC ¶ 27.

Therefore a claim cannot be processed for payment without the adjudication of the claim being impacted by the direct injection of Defendants’ reported prices into the CDP calculus, which happens when the CDHS electronic claims processing system, as initiated through the process described in Exhibit D, identifies the appropriate CDP. The CDP is, again, defined with explicit reference to prices reported by the Defendants. FAC ¶¶ 32-38. If the Defendants had not reported prices for their drugs, their drug products would not have been included in the CDHS formulary. They did report the fraudulent prices alleged in the FAC, and their prices were injected into the CDHS formulary, infecting the millions of claims at issue in the FAC.

In Exhibit B, each exemplar depicts the “Paid Amount²” for that particular sample drug

2. Exhibit B, column 7.

claim. The Paid Amount is determined in each case by EDS when it processes the claim for CDHS. EDS computers establish the Paid Amount by examining the EAC figure for the drug in the formulary, which is in turn set at a figure as described in the preceding paragraph.

Defendants knew that AWP and DP would be reported to the state and would be applied to determine EAC and therefore would be applied to the reimbursement adjudication for each claim. FAC ¶¶ 32-38. A claim cannot be paid until EDS electronically references EAC in the formulary, as alleged in the FAC. *Id.* ¶¶ 33-37. Each claim in Exhibit B for each drug example depicted therein was reimbursed by CDHS after EDS calculated the reimbursement amount with reference to the EAC, i.e., an “Estimated Acquisition Cost” set in the CDHS formulary on the basis of reported prices which were, as alleged in the FAC, false. FAC ¶¶ 27-38.

The number of Medi-Cal pharmacy claims processed by CDHS from July 1994 through March 2004 was 716 million, or, on average, 1.37 million per week. FAC ¶¶ 39-40. Under California’s Medi-Cal system, Medi-Cal pharmacy providers almost always file claims for reimbursement electronically. When submitting an electronic claim, the provider sends a stream of data to EDS, using either a “Point of Service” (POS) device provided by CDHS, or some other electronic device. CDHS’s procedural instructions to Medi-Cal providers filing a claim for reimbursement using a POS device is attached as Exhibit D, an excerpt from the CDHS Medi-Cal Provider Manual.³ For instance, on page 6 of Exhibit D, POS step/entry number 17 prompts the provider to enter its charge: “Enter your usual and customary charge for the drug in dollars and cents (even for whole dollar amounts) and press <ENTER>.” This charge is depicted for each claim line in Exhibit B in the columns captioned “billed amount”.

3. [Exhibit D is available online at http://files.medi-cal.ca.gov/pubsdoco/publications/Masters-Other/Verifone/devicesystempharm_ver00.pdf](http://files.medi-cal.ca.gov/pubsdoco/publications/Masters-Other/Verifone/devicesystempharm_ver00.pdf)

Infrequently, a provider may file a claim using a paper form as depicted in Exhibit E; however, such a “paper claim” is put into electronic format and thereafter processed electronically just as a POS claim is processed. Exhibit E is an excerpt from the CDHS’s Pharmacy Provider Manual⁴ providing instructions to Medi-Cal providers for paper claim submissions.

Exhibit B therefore provides the examples which the Court requested of Plaintiffs on May 22, 2006, i.e., an example of a single claim, which was paid by California, for each drug billed to Medi-Cal and reimbursed at a price which was fraudulently inflated due to Defendants’ actions as alleged in the FAC. Specifically, Exhibit B states the electronically recorded and processed data germane to specific claim exemplars filed by identified Medi-Cal providers for each drug included in the array of National Drug Codes (NDCs) listed in the exhibits which accompany the FAC. Exhibit B depicts information organized by columns showing (in order from left to right): (1) the Defendant manufacturer associated with the NDC listed in the claim sample; (2) the NDC for the drug reimbursed in the depicted claim; (3) the drug’s name; (4) the Medi-Cal provider’s name; (5) the claim control number for the particular sample claim reported in the Exhibit; (6) the number of units of drug in the particular actual claim sample reported in the Exhibit; (7) the amount paid by CDHS to the provider; (8) the amount billed by the provider when the provider submitted the claim to CDHS; and (9) the date the actual claim sample reported in the Exhibit was paid.

4. Exhibit E is available online at <http://files.medi-cal.ca.gov/pubsdoco/DocFrame.asp?wURL=%2Fpubsdoco%2Fpublications%2Fmasters%2DMTP%2FPart2%2Fpcf30%2D1comp%5Fp00%2Edoc>

Respectfully submitted,

BILL LOCKYER

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Dated: July 26, 2006

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on September 12, 2006, a copy to Lexis-Nexis for posting and notification to all parties.

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